(3) After the effective date on which a substance or mixture is added to §716.120, and who propose to manufacture (including import) the listed substance or listed mixture (including as a known byproduct), are required to report during the reporting period specified in §716.65.

(b) A rule promulgated under the authority of 15 U.S.C. 2607(d) may require that any person who does not fall within NAICS (in effect as of January 1, 1997) Subsector 325 or Industry Group 32411, and who had proposed to manufacture (including import) or process, had manufactured (including imported) or processed, proposes to manufacture (including import) or process, or is manufacturing (including importing) or processing a substance or mixture listed in §716.120 must report under this part.

(c) Processors and persons who propose to process a substance or mixture otherwise subject to the reporting requirements imposed by this part are not subject to this part unless EPA specifically states otherwise in a particular notice or rule promulgated under the authority of 15 U.S.C. 2607(d).

[63 FR 15773, Apr. 1, 1998]

§716.10 Studies to be reported.

(a) In general, health and safety studies, as defined in §716.3, on any substance or listed mixture listed in §716.120, that are unpublished are reportable, i.e., must be submitted or listed. However, this requirement has limitations according to the nature of the material studied, so that:

(1) All studies of substances and listed mixtures are reportable. However, in the case of physical and chemical properties, only those studies listed in §716.50 must be submitted.

(2) Studies of mixtures known to contain substances or listed mixtures listed in §716.120 are reportable except for studies of physical and chemical properties and the studies exempted at §716.20(a)(6) (i) through (vi).

(3) Studies of substances or listed mixtures that a person who is reporting has manufactured, imported, or processed or proposed to manufacture, import, or process only as impurities are not generally reportable under §716.20(a)(9).

(4) Underlying data, such as medical or health records, individual files, lab notebooks, and daily monitoring records supporting studies do not have to be submitted initially. EPA may request underlying data later under §716.40.

(b) [Reserved]

§716.20 Studies not subject to the reporting requirements.

(a) Excluding paragraph (a)(3) of this section, the following types of studies are exempt from the copy and list submission requirements of §§716.30 and 716.35.

(1) Studies which have been published in the scientific literature.

(2) Studies previously submitted to the EPA Office of Pollution Prevention and Toxics. These studies are limited to section 8(e) submissions, studies submitted during section 4 proceedings, studies submitted with premanufacture notices or significant new use notices, and studies submitted ''for your information'' (FYI submissions) in support of EPA's TSCA Existing Chemicals Program. Studies which have been initiated pursuant to a TSCA section 4(a) test rule, for which the person has submitted a letter of intent to conduct testing in accordance with the provisions of §790.25 of part 790 of this chapter, are exempt from the list submission requirements of §716.35.

(3) Except for those studies described in paragraph (a)(2) of this section, studies previously submitted to any Federal agency with no claims of confidentiality are exempt only from the copy submission requirements of §716.30, and must be listed in accordance with the provisions of §716.35.

(4) Studies conducted or initiated by or for another person who is subject to, and who will report the studies under §§716.30 and 716.35.

(5) Studies of chemical substances which are not on the TSCA Chemical Substances Inventory. This exemption applies only to those substances within categories listed under §716.120(c).

(6) The following types of studies when the subject of the study is a mixture known to contain a substance or listed mixture listed under §716.120.

(i) Acute oral toxicity studies.

(ii) Acute dermal toxicity studies.